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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,262	01/18/2002	Janice A. Brown	PC11044ADAM	1289

7590 10/21/2004

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EXAMINER

DAVIS, DEBORAH A

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/053,262	Applicant(s) BROWN ET AL.	
	Examiner Deborah A Davis	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 30, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the Office Action mailed on February 26, 2004 has been acknowledged. Currently, claims 1-3 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Decker et al (Clinical Cancer Research, Vol. 5, May 1999, pages 1169-1172) in view of Bayer et al (The avidin-biotin system, Department of Biophysics, The Weizmann Institute of Science, 1996, pages 237-267).

The claims are drawn to a method to assay PARP activity comprising contacting an immobilized PARP with NAD under conditions to allow PARP autoribosylation, wherein NAD is biotinylated or avidin-conjugated.

Decker et al teaches an ELISA assay for the detection of PARP. The assay uses no radioactivity and is reliable for screening large numbers of PARP (abstract). PARP is immobilized on a microtiter plate and contacted with NAD (page 1171, Results and Discussion). PARP becomes auto-ribosylated when it comes in contact with NAD because PARP catalyzed the transfer of the ADP-ribose moiety from NAD (page 1169, column 2, paragraph 1). After washing, PARP was detected by the addition of anti-poly(ADP-ribose) monoclonal antibody, which would form a complex (page 1171, Results and Discussion). PARP activity was measured based on the drop in PARP activity estimated by the decrease in poly(ADP-ribose) synthesis in the presence of inhibitor (abstract).

The reference of Decker et al does not teach the use of a biotin or avidin system. However, Bayer et al teaches that avidin-biotin systems improves greatly the performance of the immunoassay system and is manifested either by a substantial amplification of the signal and consequently sensitivity of the assay (introduction).

It would have been obvious to one of ordinary skill in the art to modify the teaching of Decker et al to include the use of an avidin-biotin system because it improves the performance of the immunoassay system by substantial amplification of the signal (introduction). One of ordinary skill in the art would be motivated to use avidin-biotin systems to amplify the signal of the instant assay.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Decker et al in view of Bayer et al and further in view of Craig et al (USP#6,465,199).

The teachings of Decker et al in view of Bayer et al are set forth above and differ from the instant claim in not teaching that the method to assay PARP is conducted at 4 degrees C.

However, Craig et al teaches compositions and methods for monitoring enzymatic activity of several enzymes that includes Poly-ADP-ribose that is thought to play a fundamental role in cellular signaling (col. 25, lines 1-36) DNA repair and replication (col. 26, lines 39-45). Typically, measurements for these types of assays are performed at 0-37 degrees C. or may be performed at a higher temperature if that temperature is compatible with the enzyme under study (col. 37, lines 24-32).

It would have been obvious to one of ordinary skill in the art to modify the method of Decker et al in view Bayer et al to include performing the assay at a temperature that would be compatible with the enzyme Poly (ADP-ribose) as taught by Craig et al to prevent denaturing and to allow the study of kinetic activity (col. 37, lines 24-32). One of ordinary skill in the art would be motivated to perform the instant assay at 4 degrees C. to prevent denaturing.

Response to Arguments

5. Applicant's submitted declaration under 37 CFR 1.132 filed July 30, 2004 is sufficient to overcome the rejection of claims 1-3 based upon the rejection of **35 USC §**

103 of Cheung et al in view of Schuurs et al and in further view of Metcalfe et al. A new ground of rejection has been applied to claims 1-3 above.

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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1-11-14